DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Laurence Colin
President
Crown Delta Corporation
1550 Front Street
Yorktown Heights, New York 10598

MAY 2 4 2004

Re: K940132
Trade Name: Podiatric Multi-Sil II Moldable Silicone Putty
Classification Regulation Name and Number: Limb Orthosis 21 CFR 890.3475
Regulatory Class: Class I Exempt
Product Code: MNE
Dated: March 9, 1994
Received: March 15, 1994

Dear Mr. Colin:

This letter corrects our substantially equivalent letter of September 29, 1994 regarding the classification of your device.

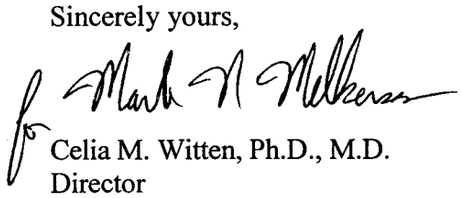
We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 890.3475. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device classification regulation name, regulatory class, and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 890.9 to determine whether or not your new device (s) meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact CAPT Marie A. Schroeder, at (301) 594-1296 or the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 442-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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